TOP GLOVE SDN. BHD. (Company No. 220483 T)
(Medical Latex Glove Manufacturer and Exporter)
Head Office & Factory 2 : Lot 4968, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D. E., Malaysia.
Tel: 603 3921992, 3921763 H/P: 012 2005955, 019 2821697 Fax: 603 3921291, 3928410
E-mail: topg@po.jaring.my, tgmed@po.jaring.my Homepage: http://topglove.asiaep.com
Factory 1 : Bangunan United Industries, Lot 5019, 5½ Miles, Jalan Meru, 41050 Klang, Selangor D. E., Malaysia.
Tel: 603-3923726, 3921101 ext:270 Fax: 603-3923726 H/P: 010-6829070
Branch : 24, Jalan Raja Mokhtar Dua, 42200 Kapar, Selangor D. E., Malaysia.
Tel: 603-3500646, 3500911 Fax: 603-3500793

AWARDED MS ISO 9002

AUG 26 '99 FRI 21 P1:33

Comment on Reg.

THE DIRECTOR
DIVISION OF SMALL MANUFACTURERS
ASSISTANCE (HFZ-220)
OFFICE OF HEALTH AND INDUSTRY PROGRAMS
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857
TEL. NO. : 001-301-443-6597 Ext. 116 Ok 146
FAX. NO. : 001-301-443-8818

August 26, 1999

Attn: Mr. John Stigi

Dear Sir,

Re: Comment on the proposed change regulation of FDA for Medical Devices

Your circular letter pertaining to the above matter refers.

We have the following comments on the proposed change regulation:-

(1) Expiration Date

In order to determine the shelf-life of different type of Medical gloves, we would appreciate if FDA can provide us the method to determine the shelf-life.

(2) Labeling for Medic31 Gloves

2.1 Powder level

The new regulation of no more than '120 mg powder per glove on the powdered surgeon's and powdered patient examination gloves is too stringent for medical glove industry as powder is necessary for easy donning purpose. We would recommend powder level to be no more than 200 mg powder per gloves which is SMG (Standard Malaysian Glove) standard

2.2 protein level

The protein level should be expressed in µg/g if it is to be appeared in labeling.
We would not agree to put content of no more than 1,200 µg extractable protein per glove in the labeling as only small group of hypersentivity individual is sensitive to allergic of natural rubber.

98N-0313 C1

ISO 9002 MALAYSIA | TÜV PRODUCT SERVICE GERMANY | NF PRANCE | CE EUROPE | FDA REGISTERED U.S.A | TGA AUSTRALIA | CGSB CANADA

Cont. page.....

The existing caution statement of protein allergy should be sufficient to warn the users on skin sensitivity problem. Further, the protein lebelling should only be meant for the manufacturer who want to claim for low protein labeling on their product.

Your kind consideration to our comments is highly appreciated as any change in FDA regulation will have great impact on the medical glove industry.

Thank you and looking forward Lo hear from you

Have a nice day

Best Regards,

Loo Sun Nooi
Assistant QA Manager

c.c. Mr. Wee-Chai Lim. Managing Director

c.c. MARGMA, Mr. Andrew Tan

LSN/Cb/FDA-5/MyDoc(Microsoft)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: August 27, 1999

From: Assistant to the Director, Division of Small Manufacturers Assistance, HFZ-220

Subject: Comments on proposed regulation
Re: Docket No. 98N-03 13

To: Dockets Management Branch, HFA-305, 5630 Fishers Lane, room 1061

Please file the attached two copies of comments under Docket No. 98N-03 13, "Surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability; Proposed Rule and Notice," which published on July 30, 1999 (64 FR 41709).

Thank you!

Arthur K., Yellin